KONAZOL

Ketoconazole Cream BP 2 % W/W

Consumer Medication Information Leaflet (RiMUP)

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What is KONAZOL used for

KONAZOL is a medicine for treating skin infections caused by fungi or yeasts.

It is used for treating skin infections on the trunk, groin, feet or hands. KONAZOL is also used to treat skin infections that usually occur on the face and on the chest with reddish brown patches and yellow or white scaling (seborrheic dermatitis).

How KONAZOL Ointment works

KONAZOL works by killing the fungus that causes the infection.

Before you use KONAZOL

- *When you must not use it*

Do not use KONAZOL if you know you are hypersensitive (allergic) to it. Symptoms of hypersentivity include itching and red skin which may occur after you have applied KONAZOL.

- *Before you start to use it*

Talk to your doctor or pharmacist before using this medicine:

- If you have recently used a cream, ointment or lotion on your skin infection that contains a steroid: You should continue to apply a mild steroid (such as hydrocortisone) cream, ointment or lotion in the morning whilst applying KONAZOL in the evening. The mild steroid treatment can then be gradually stopped over a period of 2 – 3 weeks.

If you have questions about stopping your steroid cream, ointment or lotion, ask your doctor or pharmacist.

Pregnancy and lactation
There are no known risks with the use of KONAZOL in pregnancy or breast-feeding.

Children and adolescents
KONAZOL is not recommended for use in children under 18 years of age.

- *Taking other medications*

If you are also using corticosteroids (cortisone-type medicines in cream, ointment or lotion), check with your doctor or pharmacist before starting treatment with KONAZOL. You may start with KONAZOL right away, but do not stop using the corticosteroid.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Continue your treatment as follows:

- use the corticosteroid in the morning and KONAZOL in the evening for 1 week
- after that, apply the corticosteroid in the morning every 2 or 3 days and KONAZOL every evening for another 1 to 2 weeks
- then stop using the corticosteroid and, if necessary carry on with KONAZOL only.

If you have any questions, talk to your doctor or pharmacist.

How to use KONAZOL

- *How much to use*

You should apply KONAZOL once or twice a day as instructed by your doctor. Depending on the type of infection and, treatment may last 2 to 6 weeks. Usually you will see signs of improvement after 4 weeks. If this is not the case, talk to your doctor.

For skin infections of the trunk, groin, feet and hands, apply KONAZOL once a day.

For skin infections that usually occur on the face and on the chest with reddish brown patches and yellow or white scaling (seborrheic dermatitis), apply KONAZOL once or twice a day.

Skin infections will usually get better after 2 to 4 weeks and after that you can continue to use KONAZOL once or twice a week.

• To open the tube, unscrew the cap and then pierce the seal of the tube using the pin on the top of the cap.
• Wash the infected skin and dry it well.
• Rub KONAZOL gently into the infected area and the area around the infected area with your fingertips.
• Wash your hands carefully after you have used KONAZOL, except if the treatment is for the hands.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- *When to use it*

Use as directed by your doctor or Pharmacist.

- *How long to use it*

Do not stop using the cream until a few days after all symptoms have completely disappeared.

Continue using KONAZOL for the duration that the doctor recommends.

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it. Do not apply a double dose to make up for the missed dose.

Apply the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to

apply the medicine and skip the missed dose.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

When too much KONAZOL or KONAZOL is applied more frequently than instructed by your doctor, it may cause some burning sensation, redness or swelling. If this happens, stop using KONAZOL straight away.

KONAZOL should not be swallowed. If KONAZOL is accidentally swallowed, contact your doctor.

While you are using it

- *Things you must do*

Wash your hands carefully after you have applied KONAZOL.

Keep a separate towel and flannel for your own use to avoid infecting other people.

Change clothing which comes into contact with the infected skin regularly to avoid re-infecting yourself.

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using KONAZOL.

- *Things you must not do*

Do not apply KONAZOL to eyes.

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give KONAZOL to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*.

Driving and using machines
KONAZOL is not likely to affect you being able to drive or use any tools or machines.

KONAZOL contains propylene glycol. This may cause skin irritation.

KONAZOL contains cetyl alcohol and stearyl alcohol. These may cause skin reactions such as contact dermatitis.

Side effects

Like all medicines, KONAZOL can cause side effects, although not everybody gets them. Tell your doctor if you notice any of the following side effects while using KONAZOL:

• Skin burning sensation, itching or redness

• Hyper-sensitivity (allergic) reactions, rashes, eczema, hives, irritation or other local skin reactions.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of KONAZOL

- *Storage*

Store below 30°C.

Keep the medicine out of reach of children.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

White colour smooth cream.

- *Ingredients*

- Active ingredients:
Ketoconazole BP

- Inactive ingredients:
Cetosteryl Alcohol BP, White Soft Paraffin BP, Cetomacrogol 1000 BP, Light Liquid Paraffin BP, Propylene Glycol BP, Disodium hydrogen Phosphate anhydrous BP, Disodium Edetate BP, Purified water BP.

- *MAL number(s):* MAL24096048AZ

Manufacturer

Lincoln Pharmaceuticals Ltd.
Trimul Estate, Khatraj, Tal-Kalol
382721 Gandhinagar, India.

Product Registration Holder

Healol Pharmaceuticals Sdn. Bhd. 74, 74-1, 74-2, 74-3, Pusat Bandar Wangsa Maju, Jalan Wangsa Delima 6 (1/27F), Seksyen 5 Wangsa Maju, 53300 Kuala Lumpur, Malaysia.

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